

UNII assignment and the Substance Registration System (SRS)

Thanks to Vada Perkins (CBER) and Larry Callahan and Frank Switzer (OC/OCPP) for an informative session!

SRS Information Page:

<http://www.fda.gov/ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.htm>

For questions about UNII, an additional contact: fda-srs@fda.hhs.gov

General Process:

- When you submit application – information sent to SRS for creation of UNII. Sent back to CMC other specialty reviewers to confirm, and then released to UNII list, sponsors who've been corresponding w/ FDA
- Timing stated as 4 to 6 weeks turn-around after the filing period. If it's required sooner, the request can be expedited.
- Suggestion: include in the cover letter of the submission a mention of the need for a UNII; this will provide a reminder for the Review Division.
- For vaccines, if your method of manufacturing – particularly inactivation – changes, remember to re-check and re-request UNII, as it may have changed.

Factors in UNII Assignments

- SRS works within five large categories, each with their own criteria for assignments

Substances

- Simple chemicals - based on covalent structure
- Proteins– based on protein sequence, type of glycosylation, mammalian/avian/plant
Blood factors – carboxymethylation
Example: Botox: two different names, with the same amino acid sequences
- Nucleic Acid – based on nucleic acid sequence
- Polymers
- Structurally diverse (cells, viruses) – variety of characteristics

- Information used to assign a UNII is most often in the public domain. Proprietary information characteristics have been pulled (wherever possible) from the assignment model.
- Two substances with different names can have the same UNII if the processes are different but the end-product is the same.
- Preferred Names – while there's not an official body (like USAN) for 'official names' within SRS, there are some guidelines: USAN is the first preference.
- Vaccines Preferred Name often includes inactivation methods that affect the molecular structure. Detergents such as deoxycholate don't appear to affect the molecular structure, so they aren't included in the Preferred Names
- UNII assignment for vaccines involves a set of data characteristics
- How do we know when there might be a different Active ingredient vs Active Moiety? Usually best to ask FDA. Active moiety tends to be based on what determines the strength of the product.
For live virus vaccines: same UNII for both active ingredient, active moiety

Questions / Future Possibilities

What should be done if there's a perceived error in assignment? Definitely let the Review Division know.

Since the model is much more solid than previously, the assignment process has calmed down a bit; less error in assignment.

The model has evolved to incorporate international standard requirements (e.g., ISO). Going forward, the UNII could be used as a substance identifier even outside the US.

Possibilities for the future:

- Provision of a template or form for requesting UNII: form includes criteria; sponsor can "fill in the blanks" and return as review aid.
- Future possibility of a request interface, where sponsors could request UNII's. Still a lot of discussion points for this – how to track correspondence with FDA, how 'automatic' this might be, where might it be placed, etc.
- More easily searched UNII list, ability to search SRS system would be a valuable tool for sponsors and others using UNII